National Pollution Prevention and Toxics Advisory Committee (NPPTAC)
A Federal Advisory Committee to the U.S. Environmental Protection Agency

Overview Document on Nanoscale Materials
11/22/05

I. INTRODUCTION

About two decades ago, research indicated that certain engineered nanoscale materials exhibit unexpectedly unique and novel properties. The existence of structures at the nanoscale level may confer a distinct set of physical, chemical, and biological properties. Engineered nanoscale materials are being used to improve existing products and are expected to create breakthroughs that could lead to the efficient use of resources necessary for this and future generations. EPA is interested in whether commercial activities of engineered nanoscale materials may present a potential risk to human health and the environment because of their unique physical structure and consequent properties. Therefore, EPA is considering how best to evaluate the risks associated with engineered nanoscale materials and how to manage those risks.[1]

On June 23, EPA held a public meeting to discuss a potential voluntary pilot program for reporting information pertaining to existing chemicals that are engineered nanoscale materials, and the information needed to adequately inform the conduct of the pilot program. Some public comments registered the need for a regulatory approach in addition to conducting a voluntary program. The Agency plans to move forward to develop elements of a voluntary reporting program for engineered nanoscale materials, and has asked for input from the NPPTAC on options for a voluntary pilot program and issues that may be relevant to the review of new engineered nanoscale materials under TSCA.

NPPTAC formed an Interim Ad Hoc Work Group on Nanoscale Materials to provide input to the NPPTAC for consideration at its October 2005 meeting. The Work Group charge is the development of informed discussion on the following topics:

- Options for possible elements of EPA's voluntary pilot program for existing chemical nanoscale materials.
- Approaches that may be appropriate for putting such a voluntary pilot program in place.
- Consideration of issues that may be relevant to the review of new chemical nanoscale materials under TSCA.
- Consideration of other relevant issues raised in stakeholder input provided at EPA's June 23, 2005 public meeting as well as written comments to the docket.

The Work Group met via numerous conference calls in August, September, and October 2005 and held a September 29 public session to obtain broad stakeholder input. The ten Work Group

[1] For an announcement of the June 23 public meeting see: Federal Register / Vol. 70, No. 89 / Tuesday, May 10, 2005 / Notices.

members represented small and large companies, environmental NGOs and an animal welfare organization.

The purpose of this document is to provide an overview of the Work Group's discussion and public input on some common elements of a potential voluntary program that might receive broad support, to begin consideration of regulatory actions that could be undertaken, and to flag issues for further discussion. This Overview Document was developed for discussion at the September 29 public session, which was attended by approximately 100 people, who provided comments on the broad range of issues presented by the Work Group.[2] Following the public session, the Overview Document was further revised for discussion at the October 13 - 14 NPPTAC public meeting. The Nano Work Group generally supports the approach outlined in this document, as a whole.

This Overview Document identifies, in Section VI and in Annex A, a number of issues that would benefit from further consideration. Section VI lists issues that have not been sufficiently discussed by the Work Group; and Annex A describes one issue that has received discussion by the Work Group members who held a range of views on the topic. In the text below, the issue is marked in bold as "**Issue #1**", and placed at the end of Section III.B. Voluntary Program Description, where it could be most usefully addressed.

II. GENERAL GOAL FOR EPA'S PROGRAM REGARDING ENGINEERED NANOSCALE MATERIALS

The overall goal of EPA's program regarding engineered nanoscale materials should focus on addressing the potential risks of such materials to human health and the environment, thereby giving the public reasonable assurances of safety concerning such materials. This overall goal should be executed by: a) building a baseline of information on the engineered nanoscale chemical substances, including their physical and chemical characteristics, and information on their use(s), exposure potential, and effects on human health and the environment, the tools and methods used to collect that information, and the risk management practices that are being implemented for such substances, and b) prompting implementation of appropriate risk assessment and risk management practices needed to reduce risk of potential exposures to an engineered nanoscale material during its lifecycle. With that information in hand and basic risk assessment and risk management practices in place, EPA should focus on establishing the means to assure that engineered nanoscale materials are being responsibly developed and commercialized.

Voluntary and regulatory (under TSCA) measures are being developed by EPA, in conjunction with public input. These include, for example, the nanoscale materials voluntary program (NVP); efforts to distinguish new versus existing chemical nanoscale materials; decisions on new chemical nanoscale materials notified to EPA; and Section 8(a)/8(d) reporting rules. The voluntary program, as described below, should provide statutory protections for confidential

[2] Information on the September 29 public Work Group session, including materials, a list of Work Group members, and meeting attendees including oral commentors, is available from the NPPTAC website, at: http://www.epa.gov/oppt/npptac/meetings.htm. The meeting was attended by almost 100 people. Non-Work Group attendees providing oral comment represented mostly small and large business interests and agencies. No oral comment was received from representatives of public health and worker advocates, or environmental groups.

business information, and EPA should apply a "may present an unreasonable risk" test when offering its views on specific submissions.

III. VOLUNTARY PROGRAM

The NVP is intended to encompass engineered nanoscale materials now in or soon to enter commerce and the approaches under the NVP are intended to be available to both "new" and "existing" chemical nanoscale materials, regardless of whether they would otherwise qualify for various exemptions, or fall below reporting or notification thresholds, now applicable under TSCA provisions. This scope would apply without prejudice as to whether such distinctions, exemptions, or thresholds do or should apply in other contexts beyond the duration of a voluntary program. Participation in the NVP does not supersede, rather it complements, the new chemical notification requirements for new chemical nanoscale materials.

In this context "soon to enter commerce" is defined as applying to pre-commercial new and existing chemical engineered nanoscale materials for which there is clear commercial intent on the part of the developer, excluding such materials that are only at the research stage, or for which commercial application is more speculative or uncertain.

III.A. Intended Outcomes for a Voluntary Program

New chemical nanoscale materials fall within the scope of EPA's regulatory program under TSCA section 5. EPA has started a public discussion regarding a voluntary program that would include existing and new chemical nanoscale materials.

Building on the general goals of EPA's overall program for engineered nanoscale materials[3], the Work Group identified a range of potential intended outcomes for a NVP, including:

1. Give EPA, and the public to the extent possible recognizing legitimate CBI issues, a better understanding of the types of engineered nanoscale materials; the physical, chemical, hazard and exposure characteristics of such substances; the volume of such substances; and the uses of such substances;
2. Help EPA develop capacity and a process to identify and assess risks of engineered nanoscale materials;
3. Help EPA determine what information it needs about engineered nanoscale materials and articulate those information needs to industry and other stakeholder groups;
4. Help EPA understand what risk management practices are being used at production, processing, use and disposal stages, and what additional risk management practices need to be implemented;
5. Prompt or reinforce the implementation of risk management practices; and

[3] For purposes of the NVP, engineered nanoscale materials include materials with one or more dimensions between 1 and 100 nm, that are in commerce or soon to enter commerce. Examples include, but are not limited to: nanoscale particles, fullerenes ("buckyballs"), nanotubes, nanowires, quantum dots, and nanoscale titania and other nanoscale materials that may be derived from natural sources and are further processed for use. Naturally-occurring materials that are not the result of a manufacturing process are excluded. This definition is not intended to preclude submission of information about naturally-occurring or un-intentionally-produced nanoscale materials that is relevant to understanding potential risks of engineered nanoscale materials.

6. Provide the information and experience needed to develop an overall approach to the treatment of nanoscale chemical substances under TSCA that builds public trust in nanoscale materials while enabling innovation and responsible development.

EPA might pursue a variety of actions in response to information it receives from participants. Short of a situation in which submitted information indicates an "unreasonable risk of injury to human health or the environment", in which case EPA would take actions prescribed by TSCA, EPA could pursue a range of actions, including:

1. EPA could develop a detailed and focused program for information gathering;
2. EPA could develop a process for risk assessment and risk management;
3. EPA could assess the potential risks of engineered nanoscale materials;
4. EPA could develop and call for implementation of control measures to address potential risks;
5. EPA could provide a response to information supplied by a participant to encourage greater understanding and efforts by the participant consistent with the general outcomes described above

III.B. Voluntary Program Description

EPA should establish a NVP that offers participants the opportunity to participate in a basic program, or in a more in-depth program that includes all the elements of the basic program, as well as the commitment to generate and report more in-depth information, and implement more in-depth risk management practices. EPA should develop these programs to encourage broad participation from producers[4], processors, users, and researchers, while assuring that EPA receives relevant information and achieves implementation of risk management practices adequate to achieving the overall goals stated above. Submitters of notifications on new chemical nanoscale materials should also be encouraged to commit under the NVP to meet the basic or in-depth program elements as a complement to meeting new chemical regulatory requirements.

Both of the proposed programs (Basic and In-Depth) are voluntary, and participation in either would provide specific benefits for those willing to provide information and agree to implement appropriate risk management practices. Participants would volunteer one or more specific engineered nanoscale material that they are developing, producing, processing or using, but need not necessarily volunteer all of their materials.[5] The specific information elements and management practices called for would be clearly identified by the time the voluntary program is announced. For each identified information element, participants are expected to provide to EPA all information possessed by the submitter. Information provided by participants relevant to understanding and addressing the potential risks of engineered nanoscale materials will be made publicly accessible, limited as appropriate by protections applicable to confidential business information (as described under TSCA). A schematic of the proposed NVP is provided in Annex B.

[4] For the purpose of this document, the term "producers" includes manufacturers and importers.
[5] The benefits and incentives (see Section III.C.) available for a participant could reflect the actual extent of their participation.

Basic Program Participation

Participation in the Basic Program of the NVP would consist of the following three sets of activities for each volunteered engineered nanoscale material:

1. Reporting existing (hereinafter meaning all information possessed by the submitter) material characterization information on the material as well as existing information characterizing hazard, use and exposure potential, and risk management practices;
2. Filling in gaps in basic information about material characteristics ONLY; and
3. Implementing basic risk management practices.

The general goal in designing the Basic Program would be to ensure broad participation by organizations that are able to provide relevant information to EPA.

Reporting Existing Information
A core element of the voluntary program is focused on ***reporting existing information***, meaning all information in possession of the submitting company. The information reported on each volunteered nanoscale material would include:

- **Material Characterization:** Report existing material characterization information on engineered nanoscale materials.
- **Hazard Information**: Report existing information on hazards (i.e., environmental fate and toxicity studies).
- **Use and exposure potential**: Report existing information about use and exposure potential.
- **Risk management practices:** Report existing information about risk management and other protective measures implemented now or available to be applied to engineered nanoscale materials, and to products and wastes containing such materials.

The submission of **new types of data** (including cellular, mechanistic, -omics, and human exposure) should be encouraged to provide the EPA with the range of test types that will allow them to identify the most useful ones for assessing nanoscale material toxicity and risk.

Filling Gaps in Basic Information about Material Characteristics ONLY
If some elements of a baseline set of material characterization information (the baseline would consist of the following basic material characterization information: chemical composition (including impurities), aggregation/agglomeration state, physical form, concentration, size distribution and/or surface area, and solubility) are missing, the participant in the voluntary program is expected to generate the missing information. If the physical form or state of the nanoscale material varies throughout its lifecycle (for example, solubilized particles in solvent during manufacture versus agglomerates in solidified product versus some other form after disposal) then this should be indicated and the material's characterization data that is submitted should be linked with the appropriate state of the nanoscale material. It is expected that most producers, processors, users, and researchers already have the requested information about materials characteristics. This commitment would result in only a minimal additional burden.

Implementing Appropriate Basic Risk Management Practices
Participation in the basic program would include a risk management component that consists of a participant's agreement to implement basic risk management practices or other environmental or occupational health protection controls (e.g., worker training; hazard communication (MSDS);

use of available engineering controls; provision of personal protective equipment, product labeling, customer training, waste management practices, etc.). Participants should describe their experience in implementing, and their degree of satisfaction with, Basic Program risk management practices.

In-Depth Program Participation

The In-Depth Program is for organizations (or consortia of organizations) who are interested in participating beyond the Basic Program, by generating new information about the hazards and risks (including reduction of risk) of a particular engineered nanoscale material, as well as identifying, implementing, and expanding, as needed, risk management measures appropriate for a given life cycle phase of such substance.

The In-Depth Program would be expected to focus on a more limited number of engineered nanoscale materials, generating and reporting more in-depth information as identified by EPA as necessary to allow the Agency to conduct a full risk assessment of the identified materials and associated uses. For each volunteered material, producers, processors, users, and researchers and/or consortia of such entities would submit Basic Program information and would concurrently begin to generate the additional, more in-depth information, although it is expected that it will take longer to generate the new information. In-depth information on the engineered nanoscale materials would be submitted on a prescribed set of elements, developed by EPA in advance of program launch, on material characterization, human health hazard, environmental hazard, and release and exposure. The information would be generated with an aim to avoid redundancy and ensure efficient use of resources.

Under the In-Depth program, volunteers would also agree to work to extend application of protective risk management practices identified by EPA along their supply chains, and to conduct monitoring of workplaces, environmental releases and worker health.

[Issue #1: Dispersive Uses and Handling as Hazardous Materials]

III.C. Benefits and Incentives for Participation in a NVP

The NVP needs to be structured to achieve a high level of participation and cooperation by stakeholders. A high level of participation and cooperation will provide the public with greater assurance that engineered nanoscale materials will be managed in a responsible and accountable manner. This is an important benefit of participation in the NVP, because producers, processors, users, and researchers are seeking public understanding and acceptance of engineered nanoscale materials. Participation in a program designed with broad stakeholder input and reflective of a range of needs and perspectives can provide companies with a concrete means to demonstrate their individual and collective commitment to responsible nanotechnology development. Participation also provides an opportunity to help determine the best ways to evaluate and address the potential risks of engineered nanoscale materials.

Other major benefits of participation in the NVP should be the opportunities it presents to facilitate interaction with a broader community for shared learning and experience, and to offer participants access to resources and expertise to help them implement the program. The NVP could especially encourage small companies to participate by joining with others, e.g., in consortia with their customers, to share resources and work together to satisfy the program

elements. It could also facilitate access to particular expertise (e.g., on industrial hygiene) to help implement the program in their companies or institutions.

To provide additional benefits for participation in the NVP, EPA should consider offering incentives to participants. Incentives could be differentiated between levels of participation (e.g., Basic vs. In-Depth Program participation). Incentives might include, among others:

- EPA could provide feedback regarding volunteers' submissions.
- Participants would not be required to respond to forthcoming TSCA Sections 8(a) or (d) reporting requirements specific to engineered nanoscale materials, except to the extent that the reporting requirements include data not previously submitted under the voluntary program.
- Submitters of Premanufacture Notifications (or the notices required for the applicable exemptions from the PMN requirements) that provide in their submissions all of the information called for under the NVP and agree to implement its risk management provisions would also be deemed NVP participants for that PMN upon their request. Submitters could also indicate that they wish to handle the PMN under the In-Depth Program and would be so recognized. EPA would consider this status in its review of PMN information submitted by NVP participants and may take additional steps (e.g., fast track) in the future.
- EPA should develop guidance regarding TSCA section 8(e) reportability, and other TSCA activities, regarding nanoscale materials.
- EPA should clarify how it would deal with voluntary disclosures of potential violations that are disclosed in the context of the NVP.
- Participants should be authorized to state their participation in the NVP in various promotional contexts, but not on individual products.
- EPA would maintain a website that lists program participants by name.
- In promoting outreach for participation, EPA would list, with participant permission, program participants by name (including in ads, public service announcements, or other materials intended to promote participation).
- EPA would use its best efforts to promote harmonization of information and notification requirements among federal agencies (e.g., FDA, NIOSH, OSHA, etc.) and internationally (e.g., OECD member countries).
- EPA could provide NVP participants, particularly small companies, with assistance in navigating the TSCA regulatory system.

III.D. Evaluation of the Voluntary Program and Follow-Up

The NVP should be considered an important step in assisting EPA to assess and address potential risks of engineered nanoscale materials and to achieve the overall goal set out in Section II. Therefore, the program (or at least its initial phases) should be designed as a time-limited project and evaluated by the EPA after a defined period to determine its degree of success in meeting these objectives, what lessons can be drawn from the experience, and what next steps are appropriate. The program could be designed with objectives, milestones, and regular reviews to drive success, while maintaining consistency. This would allow flexibility in evaluating needs for change and identification of lessons learned sooner rather than later, including identification of needs, means, and methods to solicit more participation.

The program will require a reasonable period of time in order to attract participants, collect data and encourage appropriate research. It is expected that EPA will determine a point in time (e.g., at 24 months) when it should conduct a full-scale program evaluation to assess:

- The degree to which the program is meeting or has achieved the overall goal of the program and its other objectives;
- The rate of participation;
- The amount and quality of information generated by the program participants;
- The adequacy and potential effectiveness of existing risk management practices; and
- The lessons and conclusions that can be drawn from the program experience, for example:
  - Characteristics of nanoscale substances that should be considered in risk assessment and risk management;
  - Which, if any, regulatory changes are needed to address nanoscale materials; and
  - Risk management practices appropriate to nanoscale substances.

Information needed for this evaluation should largely come directly from the information submitted by the program participants, but may need to be augmented with interviews with participants and other appropriate stakeholders.

Based upon these findings EPA should determine whether to continue, expand or discontinue the program and what additional steps should be taken as follow-up.

IV. REGULATORY APPROACHES FOR ADDRESSING POTENTIAL RISKS OF ENGINEERED NANOSCALE MATERIALS

A combination of voluntary and regulatory (under TSCA) measures are being developed by EPA in support of the goal of responsible development of nanoscale materials. These measures include:

- Developing a NVP;
- Developing an approach to distinguish "new" from "existing" chemical nanoscale materials;
- Preparing decisions on new chemical nanoscale materials notified to EPA; and
- Developing TSCA Section 8(a)/8(d) reporting rules.

A regulatory approach under TSCA might include the following elements.[6] The list indicates whether in the judgment of the Work Group the element should be developed in the short-, medium-, or longer term.

Near-Term

1. Defining "new" engineered nanoscale materials, specifying information needed to properly evaluate PMN (and associated exemption) notification submissions of engineered nanoscale materials. An outcome of this effort could be early consideration of element 8 below.

[6] This section is not meant to suggest a contingency, implied or otherwise, on EPA's authority to act under TSCA.

2. Ensuring public availability of information about environmental health and safety effects of engineered nanoscale materials consistent with TSCA approaches, while addressing confidential business information concerns.
3. Initiating activities to utilize TSCA Section 8(a) and 8(d) or other authorities to complement the NVP to ensure that the Agency obtains needed information about engineered nanoscale materials to inform the Program Evaluation.[7]
4. Coordinating work / responsibilities between EPA and other agencies (e.g., FDA and CPSC) to ensure appropriate coverage of engineered nanoscale materials.

Medium-Term

5. Considering whether engineered nanoscale materials added to the Chemical Substances Inventory should be identified as such, and if they should be tracked as a separate category to monitor and enable analysis of the performance of the EPA's engineered nanoscale materials program.
6. Revisiting, and revising as needed, current exemptions (e.g., LVE, LoREX, polymer) and reporting thresholds (e.g., for reporting under the IUR) available under TSCA to reflect the novel or enhanced properties of engineered nanoscale materials.
7. Utilizing TSCA authorities, as necessary, to ensure that the Agency obtains needed information about engineered nanoscale materials to inform the Program Evaluation.

Longer-Term

8. Possibly developing one or more Significant New Use Rules (SNURs) for new nanoscale uses of existing materials.
9. Promulgating one or more test rules under TSCA Section 4 to obtain further appropriate information needed to evaluate engineered nanoscale materials.
10. Implementing TSCA Section 6 or other risk reduction actions for engineered nanoscale materials found to present an unreasonable risk.

Other measures may include, but are not limited to, ensuring the development of additional information (through both the private sector and publicly accessible institutes and laboratories, such as the National Toxicology Program and other federal agencies) and implementation of control measures that EPA determines are needed to identify and manage potential risks of engineered nanoscale materials now in or soon to enter commerce.

V. IMPLEMENTATION APPROACH

This implementation approach is intended as a set of practical steps, and a proposed timeline for the implementation of EPA's program regarding engineered nanoscale materials, in order to:

- Conduct public scientific peer consultations;
- Announce the program;
- Enroll volunteers and/or engineered nanoscale materials in the NVP;
- Create opportunities for periodic communications to the public and informal check-in regarding the progress and performance of EPA's approach; and
- Conduct a robust evaluation of EPA's approach.

[7] EPA should promptly consider how to assess and address the definition of "small manufacturer or processor" for purposes of obtaining information on engineered nanoscale materials under section 8a from such entities. EPA should also consider whether changes are needed to exemptions under TSCA Section 8(d) for chemicals not listed on the TSCA Inventory to achieve the goals of EPA's program.

The implementation approach is intended to contribute to enabling broad participation in the NVP, as well as generating information about engineered nanoscale materials. An outreach program, as well as creation of benefits and incentives, is needed to generate a broad level of participation in the Basic Program. EPA is encouraged to create opportunities for stakeholder consultation and input into the development, implementation, and evaluation of EPA's program regarding engineered nanoscale materials at appropriate times.

Scientific Peer Consultation

In addition to ongoing stakeholder participation opportunities, at appropriate times during the program design and program implementation, EPA is encouraged to conduct public scientific peer consultations with specialized scientists, including from other federal agencies, such as NIOSH and the National Toxicology Program. Researchers familiar with state-of-the-art toxicity test methods, including *in vitro* methods, should be included so that new methods can be identified and included in the In-depth Program. The following questions and topics should be included in the consultations.

- Basic Program
  - What material characteristics to include in the Basic Program, and which analytical methods should be included (*to take place as soon as possible*)?
  - What basic risk management practices should be included in the Basic Program (*to take place when general structure of Basic Program has been developed by EPA, and EPA should consider the NIOSH report)*?

- In-Depth Program
  - Review and provide input on scientific and technical aspects of test methods for developing new information on hazards and risks of a particular engineered nanoscale material, including consideration of state-of-the-art methods (*to take place when general structure of In-Depth Program has been developed by EPA*).
  - Review and provide input on what additional risk management practices should be included in the In-depth Program.

- Periodic scientific peer consultation to review and take into account new scientific developments.

Implementation Timing

- Initial Sign Up Period
  - EPA should provide an initial sign-up period of six to twelve months duration, although EPA may be able to begin recruiting potential participants in advance of program launch, especially for the In-Depth Program.
  - During the initial sign-up period, entities – producers, processors, users and researchers, or consortia of these – would agree to participate in either the Basic Program or the In-Depth Program. Entities with engineered nanoscale materials either already in commerce or soon to enter commerce could sign up during this period, and they could sign up all or a subset of their materials.
  - EPA should take steps to strongly encourage sign-up during this initial period, especially by those entities with materials already in commerce, in order to

expeditiously provide EPA with as broad and deep an understanding as possible of materials in or about to enter commerce.

- Additional Sign Up Period(s)
  - An additional opportunity to sign up may be needed in a number of circumstances, for instance:
    - Additional entities may emerge;
    - Additional materials may enter commerce or approach commercialization as the program proceeds; and
    - In unusual cases, entities with materials that were already in commerce at the time of program launch may need more time to prepare to participate (e.g., due to working out details of consortia formation).
  - In providing for this second sign-up period, EPA should seek to avoid inadvertently creating an incentive for entities eligible and able to sign up during the first period to delay doing so.
  - Based on the outcome of the program evaluation (see next section) and decisions made regarding the duration of the program, EPA may wish to consider providing for additional sign-up periods, primarily to capture new entities or materials that have entered or approached commercialization after the initial sign-up periods, or the results of new research or other information that has emerged.

- Information submission by Non-Participants
  - Entities that do not sign up for the program, but have or develop, relevant information about nanoscale materials should be able to submit such information on an ongoing basis.

Program Evaluation

- OPPT should perform the robust, transparent evaluation of its approach to engineered nanoscale materials described in Section III.D. above within 24 to 27 months after the launch of the program, and if a decision is made to extend the program, periodically thereafter. EPA would solicit public input 3-4 months before the start of the evaluation, and report the results of the evaluation to the public. As appropriate, the NPPTAC is encouraged to consider if the public evaluation process should be done through NPPTAC engagement. This comprehensive evaluation should encompass the Basic and In-Depth Programs, associated regulatory measures, and international measures in which EPA has participated. NPPTAC could provide feedback to EPA.
- OPPT should provide periodic public progress reports (e.g., annually) on implementation of its approach to engineered nanoscale materials. The NPPTAC is encouraged to consider if this updating should be done via the NPPTAC. Such informal reports would be aimed at early and ongoing identification and discussion of problems or challenges.
- The NVP should be implemented with as broad participation as possible as it is intended to inform EPA and other stakeholders about the need for and nature of a more permanent approach to nanoscale materials.
- EPA should proceed with developing appropriate TSCA Section 8(a) and 8(d) rules,[8]

[8] As noted in Section IV, among the voluntary and regulatory measures being developed by EPA is the issuance of TSCA Section 8(a) and 8(d) rule(s) to ensure that EPA receives existing information from all producers about nanoscale materials. As noted in Section III.C, participants in the voluntary program

coordinated with the NVP in a timely manner to create incentives for participation in the NVP, and obtain the needed information for EPA to carry out their responsibilities under TSCA.

VI. ISSUES FOR FURTHER CONSIDERATION

There are many issues that require careful thought and consideration in structuring the EPA's nanoscale materials programs. A preliminary list of issues, and associated questions for further consideration, is presented below. This list is not exhaustive, and additional issues are anticipated.

1. Distinguishing Between "New" and "Existing" Chemical Nanoscale Materials

   How might EPA distinguish between new and existing nanoscale materials? Is there a role for "novel properties" in drawing this distinction? If so, what role? Should EPA identify (or flag) nanoscale materials on the Inventory?

   Do we have sufficient knowledge, information, and nanomaterial terminology at this time to make the distinction of when an "existing" nanoscale material's molecular identity is sufficiently altered to become a "new" nanoscale material?

2. Enhanced Properties

   A particular property may be enhanced as a nanoscale material. Is there a role for enhanced properties in drawing a distinction between "new" and "existing" nanoscale materials?

3. Inventory of Engineered Nanoscale Materials

   Should EPA build/publish an inventory of nanoscale materials? Should the EPA provide clarifying descriptive language to inventory listings of nanoscale materials that are more explanatory of physical forms and properties? See also Overview Document, Section IV, bullet 1.

4. Inventory Update Rule (IUR)

   EPA has a periodic reporting requirement known as Inventory Update Rule (IUR) for existing chemicals meeting certain production and other requirements. If EPA undertakes to flag nanoscale materials as described under Issue #1, should EPA make special efforts to obtain reporting on such nanoscale materials. If so, how might such nanoscale materials be considered under the IUR?

5. Public Access to Information

   Assuming protection of confidential business information (CBI), what type of information would be most useful for the public? At what level of detail should information be provided to the public? Would data summaries from the voluntary submitters be adequate and informative? Should data reviews by EPA be included?

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should be exempted from having to submit the same information under these rules that they have already submitted under the NVP.

6. Data Management for Submitted Information

What types of information on nanoscale materials should be included in the NVP? Should EPA develop a standardized format for submission of information? Could such a format, after some experience, serve a purpose as a structure for an NCAN[9]?

What mechanism should EPA consider to manage the information in a timely manner? How can information be shared with stakeholders and the public?

7. Labeling/Material Safety Data Sheets

EPA may regulate new chemical nanoscale materials by requiring specific MSDS language. How is information on nanoscale materials that are existing chemicals passed on to downstream users? Working with other agencies as needed, should EPA offer guidance and assistance to companies to make Material Safety Data Sheets and labels for nanoscale materials more informative? If so, how?

8. Data Compensation[10]

Data generated under TSCA Section 4 rules are compensable. Data voluntarily generated under TSCA are not compensable through an EPA process. Should a data compensation system be considered for development under the NVP to provide an incentive to parties who wish to generate data, and whose competitors might benefit from such data?

How can information reported under the NVP be shared among stakeholders while seeking to preserve a data submitter's claim to data compensation and at the same time meeting needs for potentially limiting the use of and public access to such information.

9. PMN Data Requirements

What information should accompany PMN submissions for new nanoscale materials? Should the information be different for nanoscale materials that are also included in the NVP? If so, how?

10. Supply Chain

What factors might different actors in a nanomaterial supply chain – producers, processors, manufacturers of articles that incorporate nanoscale materials – consider in deciding whether to participate in the NVP individually or in a consortium with others in their supply chain?

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[9] Analogous to the Microbial Commercial Activities Notices (MCAN), a specialized reporting system for products of biotechnology.

[10] Data compensation is a mechanism that provides for cost-sharing of the cost of developing new information on a material among producers/processors/users of the given material. TSCA provides for compensation to be made to data generators under TSCA Section 4 test rules and authorizes collection from those who did not sponsor the information.

How could EPA ensure or encourage the sharing of information and the application of appropriate risk management practices across nanomaterial supply chains?

11. Exemptions (see also first paragraph in Overview Document, Section III. Voluntary Program)

TSCA provides for certain exemptions from PMN requirements under Section 5(h)(4), e.g, R&D, LVE, LoREx, certain polymers (LVEs and LoREx, however, still require a notification to EPA for a case-to-case determination). Should EPA revisit the applicability of these exemptions on nanoscale materials?

TSCA also includes exemptions from reporting under Section 8(a) for small businesses. These exemptions may be lifted if EPA takes certain actions pursuant to provisions of TSCA Sections 4, 5, 6, or 7. Should the regulation be developed so as to not exclude participation by small businesses? If so, how?

12. EPA Resources

What steps is OPPT taking to allow it to deal with nanoscale materials? What else could EPA do to deal with nanoscale materials?

13. Aggregation and Agglomeration of Nanoscale Materials

Should the potential of nanoscale materials to aggregate, disaggregate, or agglomerate affect how their risks ought to be considered?

14. Retaining Samples of Nanoscale Materials as an Element under the NVP

Should NVP participants be encouraged to retain a sample of the material for which the company has submitted data to the EPA? What are the implications, benefits and challenges of including this aspect in a NVP (e.g., would this enhance the effectiveness of the NVP; can nanoscale materials be stored appropriately and be available in the same form for later analysis without this being a requirement of the NVP, etc.)?

15. Further Define and Clarify Attributes of the In-depth Program

How would the In-depth Program differ from the Basic Program? What additional information should be generated under the In-Depth Program? How should new data be generated (i.e., what types of tests, assessments methods, etc. would be used)? How would EPA review/interpret data received under the In-Depth Program?

How could grouping of nanoscale materials (by type or by use) be used to make data generation more efficient and also to inform data interpretation?

16. Should there be further benefits to In-Depth Program participation, for instance EPA acting "faster" on PMN submissions?

Since participants in the In-Depth Program would do more work than participants in the Basic Program, should participants in the In Depth Program receive more benefits than

participants in the Basic Program? If so, what might those benefits be? Should EPA consider developing these elements?

17. Small Business Considerations and Concerns

What assistance could the EPA (and voluntary program participants) provide to small businesses regarding understanding and implementing of: TSCA requirements; information provision under the NVP; and risk management practices to protect worker health and the environment? How can this assistance best be provided? Should EPA explore with the Small Business Administration (SBA) and the US Patent and Trademark Office (U.S. PTO) the ideas raised in public comment regarding potential opportunities for incentives to participation in the NVP?

ANNEX A: REMAINING ISSUE FROM OVERVIEW DOCUMENT

A range of issues, program elements and approaches to program implementation have been discussed by the Nano Work Group and are presented in the Overview Document. This Annex previously contained a number of issues and questions that were discussed by Work Group members, and on which Work Group members held a range of opinions. At the conclusion of the Work Group discussions, the Work Group had addressed many issues and questions, and incorporated relevant language in the body of the Overview Document. At this time, Work Group members continue to hold a range of opinions on the issue of dispersive uses and handling of nanoscale materials as hazardous materials. A few options regarding this issue are presented below. In addition, the Overview Document, Section VI. lists issues that *have not* been discussed extensively by the Work Group.

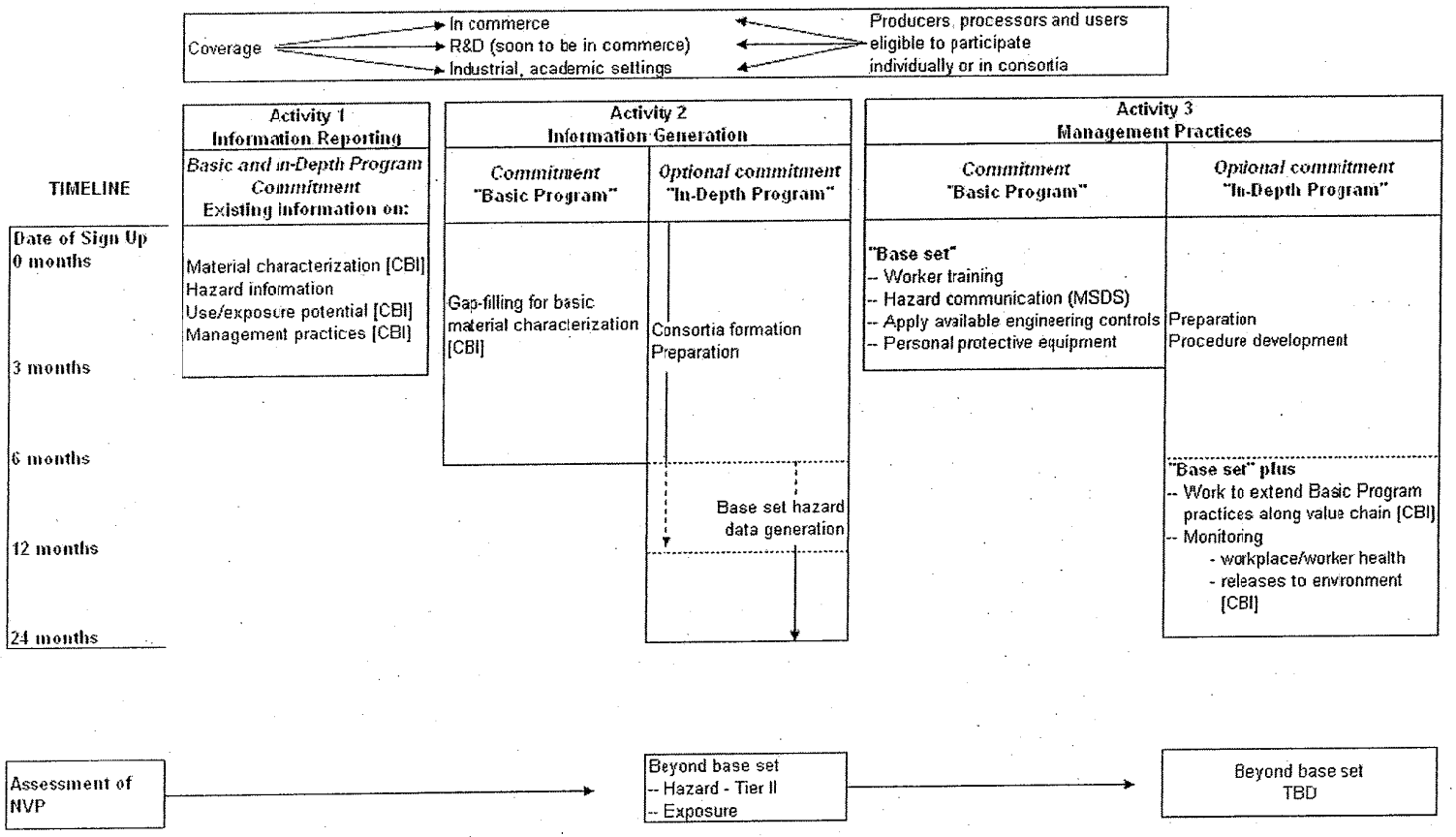
III. Voluntary Program

Issue #1: Dispersive Uses and Handling as Hazardous Materials

As additional commitments for In-Depth Program participants of the NVP, should they be expected to:

a) refrain from introducing into commerce any products that involve dispersive uses of engineered nanoscale materials, until and unless they have developed and provided to EPA hazard and exposure information sufficient to allow it to identify, assess and address the lifecycle risks of the nanomaterials in products; and
b) handle all nanomaterials as hazardous materials, and manage all wastes containing such materials as hazardous wastes, until and unless they have developed and provided to EPA hazard and exposure information sufficient to allow it to identify, assess and address the lifecycle risks of the nanomaterials and wastes in manufacturing, or
c) take on no additional commitments?

ANNEX B: COMMITMENT TIMELINE AND COMPONENTS OF NVP



* [CBI] = Information areas where CBI protections may be needed or appropriate